

the directions, "one 4 times a day," borne on the labeling, were not adequate directions for use; and, Section 502 (j), the article was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in its labeling.

DISPOSITION: December 4, 1945. A plea of guilty having been entered, the court imposed a fine of \$500 and sentenced the defendant to serve 3 months in jail. The jail sentence was suspended and the defendant was placed on probation for 6 months.

1702. Adulteration and misbranding of boric acid ointment. U. S. v. S. Pfeiffer Manufacturing Co. and John A. Mueller. Pleas of nolo contendere. Corporate defendant fined \$200; individual defendant fined \$20. (F. D. C. No. 16593. Sample Nos. 5625-H, 5626-H.)

INFORMATION FILED: November 13, 1945, Eastern District of Missouri, against the S. Pfeiffer Manufacturing Co., a corporation, St. Louis, Mo., and John A. Mueller, plant manager for the corporation.

ALLEGED SHIPMENT: On or about October 7, 1944, from the State of Missouri into the State of Connecticut.

PRODUCT: Examination of samples disclosed that the product did not contain any boric acid, but that it contained, in the two samples examined, 0.3 percent and 0.58 percent, respectively, of oil of mustard.

LABEL, IN PART: "Gold Medal * * * Boric Acid Ointment U. S. P."

NATURE OF CHARGE: Adulteration, Section 501 (d), a substance containing oil of mustard had been substituted in whole or in part for "Boric Acid Ointment U. S. P."

Misbranding, Section 502 (a), the label statements, "Boric Acid Ointment U. S. P." and "A soothing emollient ointment for Chafing, Bruises, Sunburn, Minor Burns and Scalds, and Minor Skin Irritations * * * Cleanse affected area well and apply ointment once or twice daily. Cover with clean gauze or bandage if possible," were false and misleading since the article was not "Boric Acid Ointment U. S. P.," and it was not a soothing emollient ointment for the conditions stated.

Further misbranding, Section 502 (j), the article, because of the presence of oil of mustard, was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, and suggested in the labeling, "cleanse affected area well and apply ointment once or twice daily. Cover with clean gauze or bandage if possible."

DISPOSITION: January 15, 1946. Pleas of nolo contendere having been entered on behalf of the defendants, the court imposed upon the corporate defendant a fine of \$100 on each of 2 counts; and the court also imposed upon the individual defendant a fine of \$10 on each of 2 counts.

NEW DRUG SHIPPED WITHOUT EFFECTIVE APPLICATION

1703. Misbranding of Hyatrone Androgenic Hormone Preparation. U. S. v. 20 Jars of Hyatrone Androgenic Hormone Preparation, and an accompanying booklet. Default decree of condemnation and destruction. (F. D. C. No. 19013. Sample No. 7323-H.)

LABEL FILED: January 28, 1946, District of New Jersey.

ALLEGED SHIPMENT: From New York, N. Y., by the Johay Corporation. The product was shipped on or about August 4, 1945, and the booklet was shipped subsequent to that date.

PRODUCT: 20 jars of *Hyatrone Androgenic Hormone Preparation* at Hohokus, N. J., together with a booklet entitled "Hyatrone * * * Hormone Preparations for Men and Women."

LABEL, IN PART: "Hyatrone Androgenic Hormone Preparation Contains 36,100 MG Pure Crystalline Testosterone."

NATURE OF CHARGE: Misbranding, Section 502 (a), certain statements on the labels of the article, in the booklet, and in a letter addressed to the consignee by the Johay Corporation, were false and misleading since they represented and suggested that the article would combat old age, compensate hormone deficiency, prolong the prime of life, restore the vigor of youth, build new tissues, promote endurance, improve mental capacity, stimulate new strength, correct impotency, and renew confidence. The labeling represented further that the article would

abolish the troublesome symptoms associated with the male climacteric occurring during middle age; that it would be efficacious in the treatment of emotional instability, despondency, irritability, fatigability, insomnia, diminution of mental powers, hearing, and potency, and, in severe cases, flushes and sweats; and that it would be useful in cases of benign prostatic hypertrophy, for the relief of pain in certain forms of heart disease, such as angina pectoris, and for the improvement of peripheral circulation in certain arterial diseases, such as arteriosclerosis. The labeling also represented that use of the article would result in a clearer brain, better hearing, a stronger voice, improved resistance of the nervous system against fatigue, promotion of muscular development, strength, and endurance, and increased potency. The article would not be effective to fulfill the promises of benefit stated and implied.

Violation of Section 505, the article was a new drug which should not have been introduced into interstate commerce since it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions suggested in its labeling, "Massage into skin $\frac{1}{2}$ level teaspoon of Hyatrone until completely absorbed. Repeat this treatment each morning and night for six consecutive days. Stop treatment for five days. Resume treatment for six days. Discontinue for fourteen days and begin cycle anew until results are satisfactory. Thereafter only $\frac{1}{2}$ level teaspoon is required as a maintenance dose in the above cycle"; and an application filed pursuant to law was not effective with respect to the article.

DISPOSITION: February 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

DRUGS ACTIONABLE BECAUSE OF CONTAMINATION WITH FILTH

1704. Adulteration of Comfort's Spiced Bitters. U. S. v. Aschenbach & Miller, Inc., and Laurence W. Helweg. Plea of nolo contendere. Corporation fined \$500; imposition of sentence upon the individual defendant was suspended, and he was placed on probation for 30 days. (F. D. C. No. 16606. Sample No. 3427-H.)

INFORMATION FILED: November 29, 1945, Eastern District of Pennsylvania, against Aschenbach & Miller, Inc., Philadelphia, Pa., and Laurence W. Helweg, secretary and treasurer of the corporation.

ALLEGED SHIPMENT: On or about January 18, 1945, from the State of Pennsylvania into the State of Virginia.

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of rodent hair fragments and insect fragments; and, Section 501 (a) (2), it had been prepared under insanitary conditions whereby it may have become contaminated with filth.

DISPOSITION: March 25, 1946. Pleas of nolo contendere having been entered, the court imposed a fine of \$500 against the corporation. The court suspended imposition of sentence upon the individual defendant and placed him on probation for 30 days.

1705. Adulteration of buchu leaves. U. S. v. 3 Bales of Buchu Leaves. Default decree of condemnation and destruction. (F. D. C. No. 19100. Sample No. 35613-H.)

LABEL FILED: February 12, 1946, Eastern District of Missouri.

ALLEGED SHIPMENT: On or about December 6, 1945, by R. J. Prentiss and Co., from New York, N. Y.

PRODUCT: 3 bales, each containing 280 pounds, of *buchu leaves* at St. Louis, Mo.

LABEL, IN PART: "E. M. & Co. Produce of Union of South Africa Buchu Leaves With Stems."

NATURE OF CHARGE: Adulteration, Section 501 (a) (1), the article consisted in whole or in part of a filthy substance by reason of the presence of insects and insect fragments.

DISPOSITION: March 25, 1946. No claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.